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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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JONES DAY				
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NEW YORK, NY 10017				
EXAMINER				
ROGERS, JAMES WILLIAM				
ART UNIT		PAPER NUMBER		
1618				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/980,727

Applicant(s)

REIN ET AL.

Examiner

JAMES W. ROGERS

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 5, 6, 10, 16-18 and 20-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5-6, 10, 16-18, and 20-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-884)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/22/2008 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10,16-18,23-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakamichi *et al.* (EP 0,580,860 A1, cited by applicants).

Nakamichi teaches a method of manufacturing a pharmaceutical solid dispersion by the use of a twin screw type extruder. See abstract. The solid dispersion was produced without heating chemicals and polymeric carriers above their respective melting points. The polymeric carriers included virtually any natural or synthetic polymers including starch and processed starch. See page 3 lin 8-19. The drugs which

could be incorporated into the dispersion were not particularly limited and the specification listed numerous examples. See page 4 lin 1-page 6 line 48.

Claims 10,16-17,23-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Lentz *et al.* (WO 92/15285), for the reasons set forth in the office action filed 05/11/2007.

Response to Arguments

Applicant's arguments filed 11/12/2007 have been fully considered but they are not persuasive. Applicants assert that their presently pending claims relate to a method for producing a controlled release matrix that requires co-extrusion of a dry mixture of starch and an active agent at a die temperature below 100°C. Applicants assert the only example within Lentz which employed co-extrusion of starch and an active led to a foamed product not a vitrified product. Applicants further argue that the active ingredient within Lentz is not processed with the starch but is merely combined with the starch after processing. Furthermore applicants assert Lentz product is soft and rubbery and is thus above the glass transition temperature. Furthermore applicants assert that Lentz prefers that the process to heat the composition is above the glass transition temperature, and this is in contrast to applicant's invention in which the composition is vitrified, thus applicants state its temperature never exceeded the glass transition temperature.

Firstly the examiner notes that for the claims rejected above applicants do not claim a method of making a sustained release matrix but rather the claims are drawn to

a controlled release matrix. The steps of producing the matrix within the rejected claims above are attempts to limit the claims by product by process. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Since the matrix of Lentz is within the scope of applicants claimed invention the matrix of Lentz anticipates applicant's invention. Furthermore In regards to applicants assertion that the only co-extrusion process within the examples is a foamed product and the product within the examples is soft and rubbery, these arguments are not found persuasive since the examples within Lentz were given solely for the purpose of illustration and were not to be construed as being limiting to their invention since many variations are possible without departing from the spirit and scope of the invention. Clearly Lentz describes that the starch could be in several physical forms depending on the processing temperature including melts and/or thermoplastic materials which would not be physically rubbery or soft, rather upon cooling they would be glass-like. Example 18 is only one very limited embodiment of the Lentz reference, a vaginal suppository and clearly is not limiting for the entire scope of the reference which teaches numerous final products besides the narrow product described within claim 18. In regards to applicant's assertion that the active ingredient is not processed with starch, this assertion is false, Lentz clearly teaches that the active ingredient may be

added to the starch prior to destructureization process (the processing step of the starch). See page 13 lines 5-22. Regarding applicants statement that their product is never raised above the glass transition temperature, firstly this argument would seem to be of little relevance since applicants do not recite such a limitation on the temperature within claims 10 or 25. Secondly as stated in the previous office actions Lentz teaches a range of temperatures to process the starch and specific examples within the experimental section describe processes that are within applicants claimed temperature range. It is also noted by the examiner that claim 6 states the shear force, temperature and pressure are modified to achieve glass transition of the starch, thus it would appear that applicant's matrix should be processed at the glass transition temperature. Thus it is inherent that since the processing could use the same a temperature within applicants claimed range and the technique of co-extrusion was taught within the reference one of ordinary skill in the art at the time of applicants claimed invention would have immediately envisaged applicants claimed invention since the temperature and the technique of processing starch in combination with an active was taught by Lentz.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 5-6, 10, 16-18, and 20-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamichi *et al.* (EP 0,580,860 A1).

Nakamichi is disclosed above. Namamichi is silent on the specific temperatures of the extruder during the extruding process and the amount of water added to the mixture during processing. Nakamichi does disclose however that processing parameters such as pressure, temperature, feed rate of material, amounts of water, plasticizer and other additives are dependent on the type of drug and polymer, the twin screw extruder model used and other conditions. See page 3 lin 24-29. Nakamichi further discloses that it is important to select a combination of parameters such that the drug, polymer ect. will be maintained at temperatures below their decomposition points and vary the operating parameters according to the desired characteristics of the product. Thus the temperature of the extruder and amount of water added to the mixture to be extruded is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal temperature of the extruder and amount of water added to the mixture to be extruded in order to best achieve the desired characteristics of the product. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of temperature and amounts would have been obvious at the time of Applicant's invention. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover

the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.”); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969).

Claims 1, 5-6, 10, 16-18, and 20-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz *et al.* (WO 92/15285), for the reasons set forth in the office action filed 05/11/2007.

Response to Arguments

Applicant's arguments filed 11/12/2007 have been fully considered but they are not persuasive. Applicants assert the examiner was misguided in applying MPEP §§ 2111 and 2123 to mean that the examiner can reasonably create a teaching by extrapolating a disclosed embodiment to a broader teaching without any further guidance. Applicants assert that the processing temperature range to which the examiner is citing means the entire process occurs at temperatures encompassing any temperature between 80°C to 240°C, but rather means that the entire process occurs at temperatures encompassing 80°C to 240°C, never just 80°C or 130°C or 240°C. Applicants assert the reference is referring to the range of temperatures of the extruder, the temperatures varying at different locations of the extruder. Applicants assert there are no details within the specification on how co-extrusion is carried out unless it is carried out by the same method that Lentz uses to extrude the starch alone. Applicants assert one such teaching is example 18 which does not provide details of co-extrusion

and it teaches co-extrusion of not starch but molecularly dispersed starch (MDS) with an active. Applicants further assert that the result of claim 18 was a foamed rubbery product and not vitrified as required within the claims. Applicants assert Lentz does not suggest a modification of the orifice of the extruder to be below 100 °C at normal pressure, thus applicants surmise it is unreasonable for the examiner to extrapolate the disclosure of Lentz to suggest the co-extrusion of starch and an active agent at a die temperature less than 100 °C. Applicants further assert in regards to the examiners last action that example 11 uses a preferred temperature range of 110°C to about 100°C but this process uses MDS not native starch. Applicants lastly submit that the last declaration of Dr. Rein does cover the entire breadth of the claims because the experiments from the specification disclose the full temperature profile claimed and Dr. Rein provided other experiments with die temperatures of 97°C, 100°C, 102°C and 114°C.

Firstly, the examiner respectfully disagrees in regards to applicants assertion that the examiner has extrapolated a broader meaning for the recitation of the temperature range cited throughout Lentz to mean that any temperature between 80-240°C for the orifices temperature could be selected and that this is in reference to the entire range of temperatures within the extruder. Firstly there are two specific examples in figure 10 in which the processing temperature for the controlled release formulation was 70°C and 100°C within applicants claimed range, these two examples show that contrary to applicants assertion the processing was carried out at either a constant temperature or at least a final temperature that is below applicants claimed upper limit. Thus applicant's

assertion above that the temperature range is merely referring to the range of the entire extrusion process is not found persuasive since the examples clearly demonstrate that the processing temperature for at least two examples was below applicants claimed upper limit. Applicant's assertion that there are no details within the specification on co-extrusion with an active besides example 18 is also not persuasive, clearly as recited in the previous office actions and above Lentz discloses co-extrusion of both the active and starch together during processing. The examples within Lentz such as example 18 were given solely for the purpose of illustration and were not to be construed as being limiting to their invention since many variations are possible without departing from the spirit and scope of the invention. Applicants assertion regarding example 11 which they purport to show that Lentz uses MDS starch when the temperature was about 110°C to about 100°C is also not found persuasive because once again applicants are interpreting the examples to be limiting to the scope of the invention of Lentz, when clearly the reference does describe processing the starch and active together, before the formation of MDS. Regarding applicants last assertion that the declaration and specification does cover the entire breadth of the claims, this is not found persuasive because the specifications examples only use 3 specific temperatures 65, 80 and 95 °C, while applicants declaration performed the experiment at temperatures of 80-80-80 and die temperatures at the high end of the claimed temperature limit of 97 and 100 °C. Because only a few examples was given by the applicant to show the results that would demonstrate patentability over the prior art, it is difficult to see how this properly illustrates results that are unexpected over what has been broadly taught by Lentz *et al.*

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618